

REMARKS

A. Status of the claims

Claims 1-69 are currently pending and under examination and claims 70-73 have been withdrawn from consideration. No amendment to the claims has been made herein.

B. Rejection of the claims under 35 U.S.C. §103 should be removed

In the instant Office Action the Examiner has rejected the subject matter of claims 1-69 under 35 U.S.C. §103 as allegedly rendered obvious over a single reference, Huyghe et al. 1995. However, the Examiner has failed to make a *prima facie* case for obviousness under 35 U.S.C. §103 and therefore also failed to shift the evidentiary burden to the Applicants.

In particular §2142 of the Manual of Patent Examining Procedures (MPEP) states that:

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP §2142

In order to establish a *prima facie* obviousness, the Examiner must identify how the prior art reference(s) teach or suggest all the claim limitations (*see, e.g.*, MPEP §706.02(j)).

Furthermore, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). In the instant rejection, the Examiner cites Huyghe et al. and states that Huyghe et al. “teaches a variety of different chromatographic methods for purifying adenovirus.”

However, the rejection fails to point out where Huyghe et al. teaches **any of the elements** of any of the pending claims, much less how Huyghe et al. teaches or suggests **all elements** of the instant claims as required to reach a conclusion of *prima facie* obviousness. For example, it has not been identified how Huyghe et al. teaches a “chromatographic medium [that]

retains one or more contaminants from said [virus] eluate.” In view of this shortcoming Applicants assert that no *prima facie* case has been made in the rejection and the Examiner has failed to shift the burden to the Applicants.

Moreover, because the rejection fails to identify prior art teaching of all claim elements, it likewise fails to demonstrate that elements could be combined as claimed with predictable results. The requirement for such predictable combination of elements to formulate a *prima facie* obviousness rejection is clearly set forth in language from *KSR International Co. v. Teleflex Inc.* that is quoted by the Examiner in the instant rejection and states:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007)

Thus, in addition to its failure to identify teaching or suggestion all claim elements in the prior art, the rejection fails to demonstrate how their combination would be predictable and result in “anticipated success.” The standards set forth in the by the KSR court indicate that *prima facie* obviousness of the claims has not been established in the rejection. Even if the rejection identified a teaching or suggestion of all elements of the claims in the prior art it still fails to demonstrate that the skilled artisan would recognize these elements as predictably combinable for adenoviral preparation as claimed. According, Applicants request that the rejection be removed.

The forgoing arguments notwithstanding, Applicants further assert that the instant rejection has been improperly applied to all of the pending claims in the case. As outlined above, in order to form a *prima facie* case for obviousness the Examiner must identify how cited reference(s) teach or suggest all elements of the claims. However, the grounds for the rejection fail to identify how *Huyghe et al.* teaches any of the elements of the instant claims much less all elements of all claims. For instance, no teaching or suggestion concerning the use of dye affinity media in the purification of adenovirus (*see, e.g.*, claims 6-

8, 20-22 and 30-32) has been identified in Huyghe *et al.* or any other reference. Similarly, no teaching or suggestion has been identified in Huyghe *et al.* or any other reference regarding the use of heparin affinity media for use in chromatographic purification of adenovirus (*see, e.g.,* claims 34 and 35). Thus, even if a *prima facie* rejection of some claims was made by the Examiner, and it was not, the Examiner has improperly failed to show how the rejection is applied to all pending claims.

C. Conclusion

In view of the above amendment and argument, Applicants believe the pending application is in condition for allowance and such favorable action is requested. The Examiner is invited to contact the undersigned to discuss the case.

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Respectfully submitted,

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